

Development of a Totally Implantable Electromechanical Total Artificial Heart: Baylor TAH

Setsuo Takatani, Motomi Shiono, Tatsuya Sasaki, Julie Glueck, George P. Noon, Yukihiro Nosé, and Michael E. DeBakey

Department of Surgery, Baylor College of Medicine, Houston, Texas, U.S.A.

Abstract: A totally implantable, one-piece, electromechanical total artificial heart (TAH) intended for permanent human use has been developed. It consists of left and right pusher-plate pumps (63 cc design stroke volume) sandwiching a thin center piece with a compact electromechanical actuator. The pusher-plates are shaped conically to accommodate an actuator in the space between them. The actuator consists of an efficient and durable planetary roller screw and direct current brushless motor. The left master alternate pumping mode was implemented utilizing the left pump pusher-plate position signal. The blood-contacting surface was coated with a dry gelatin to yield long-term clot-free performance. Trileaflet tissue valves of 27 and 23 mm are used in the inflow and outflow ports. The diameter and thickness of the TAH are 97 and 82 mm,

the overall volume is 510 cc, and the weight is 620 g. Anatomic fit was confirmed in 26 heart transplant recipients (body weight 78 kg and surface area 2 m²) without compressing adjacent organs. The pump performance study revealed that the TAH can yield outputs of 3–8 L/min against the 100 mm Hg afterload with 1–10 mm Hg filling pressure. The input power to the motor ranged from 7 to 12 W, with an efficiency of 18% to 14%. A one-week in vivo calf study demonstrated adequate performance of the TAH, particularly the regulation of atrial pressures. Good anatomic fit and good biocompatibility were also demonstrated. **Key Words:** Electromechanical total artificial heart (TAH)—One-piece TAH—Left master alternate pumping—Heart transplantation—Dry gelatin coating.

Mechanical hearts, both pulsatile and nonpulsatile, have been gaining acceptance among cardiac surgeons as a means of supporting patients' circulation. For temporary support following open heart surgery, extracorporeal devices such as Biomedicus centrifugal or pneumatic pulsatile blood pumps have been used with favorable outcomes (1,2). However, prolonged support over months or years, either bridging to heart transplantation or supporting the patients' circulation indefinitely, imposes severe requirements on the devices from medical, engineering, and socioeconomic points of view (3,4). These requirements include compact shape and low weight, antithrombogenic properties, extended mechanical durability, high efficiency, totally im-

plantability, and low cost. Although several devices are used currently as cardiac assist or replacement devices, further research is needed to develop devices better suited for permanent application (2,3,5).

The overall objective of this research is to develop a totally implantable electromechanical TAH intended for permanent use. This paper describes the design, in vitro evaluation, and preliminary in vivo evaluation of the Baylor electromechanical TAH.

BASIC DESIGN CONCEPT

Figure 1 shows the anatomical placement of the TAH. In order to obtain a compact, durable, and highly efficient design, a conically shaped pusher-plate blood pump, driven by an electromechanical actuator utilizing a direct current (DC) brushless motor and a planetary roller screw, was proposed. The TAH is a one-piece design with the left and right pumps being driven alternately by a compact actuator between them. A Hexsyn rubber diaphragm will be used to ensure high flex life (6). The blood-

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Address correspondence and reprint requests to Dr. S. Takatani, Associate Professor, at Department of Surgery, Baylor College of Medicine, One Baylor Plaza, Houston, TX 77030, U.S.A.

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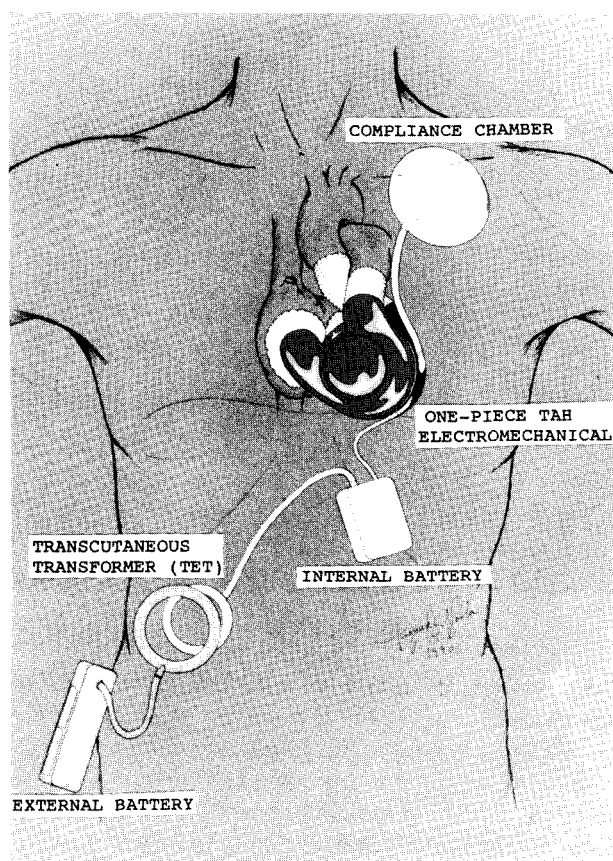


FIG. 1. Anatomical placement of totally implantable artificial heart and its related components.

contacting surface will be coated by a dry gelatin to ensure long-term clot-free performance (7). Tissue valves are used in the inflow and outflow ports to obtain high pumping efficiency and long-term performance. The external contour and port angulation will be designed to obtain good flow patterns and to suit patients' anatomy. The control-drive system is made into an implantable size, utilizing very large scale integrated (VLSI) circuit technology. The energy is supplied transcutaneously utilizing a pair of coils. An internal battery will allow 30–40 min of operation in case a physical need develops to remove the external power transmitter or the external energy system malfunctions. The external portable battery should run the device for 7–8 h continuously and will be recharged as required from the power line.

MATERIALS AND METHODS

Baylor total artificial heart

Pumping unit

Figures 2 and 3 show the assembled electromechanical Baylor TAH and its schematic drawing.

Figure 4 shows the left and right pump housings, the center piece with an actuator, and conically shaped pusher-plates with Hexsyn rubber diaphragms before final assembly. The external diameter of the TAH is 97 mm, with a central thickness of 82 mm (8). The Baylor TAH consists of left and right pusher-plate-type blood pumps (design stroke volume of 63 cc with 0.5 inch stroke) sandwiching a thin center piece (18 mm) with a compact actuator. The pusher-plates were shaped conically to optimize the overall volume (510 cc), to minimize in particular the distance between the two pumps (center piece 18 mm thick), and to accommodate a compact actuator in the space available between them. Hexsyn rubber was used as a diaphragm because of its high flex life of over 350 million cycles. The blood-contacting surface, including the inner surface of the pump housing and diaphragm, was coated with glutaraldehyde-treated calf-skin gelatin. This wet gelatin coating was proved both experimentally (for 10 months) and clinically (for 5 months) to provide an antithrombogenic property to cardiac prostheses. The dry gelatin procedure was developed to circumvent the sterilization and storage problems of the wet gelatin. In the inflow and outflow ports, 27 and 23 mm low-profile bovine pericardial tissue valves were used. Thus, the entire blood-contacting surface of the Baylor TAH is made of materials originating from natural tissues.

The electromechanical actuator consists of a DC brushless motor (Sierracin/Magnedyn) and a planetary roller screw (SKF, France). The rotational motion of the motor is translated to a rectilinear motion of the roller screw. A circular plate with three

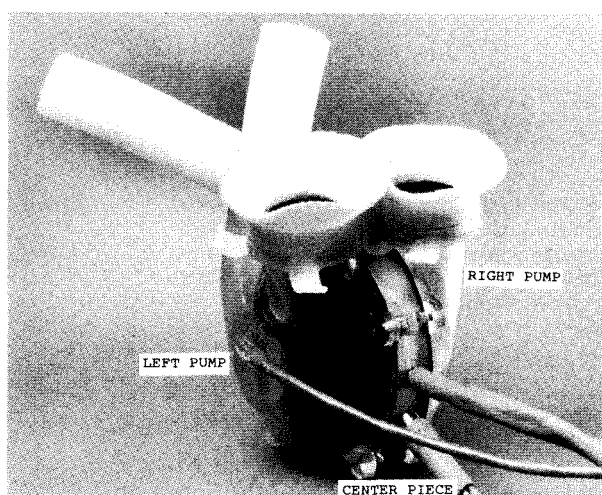
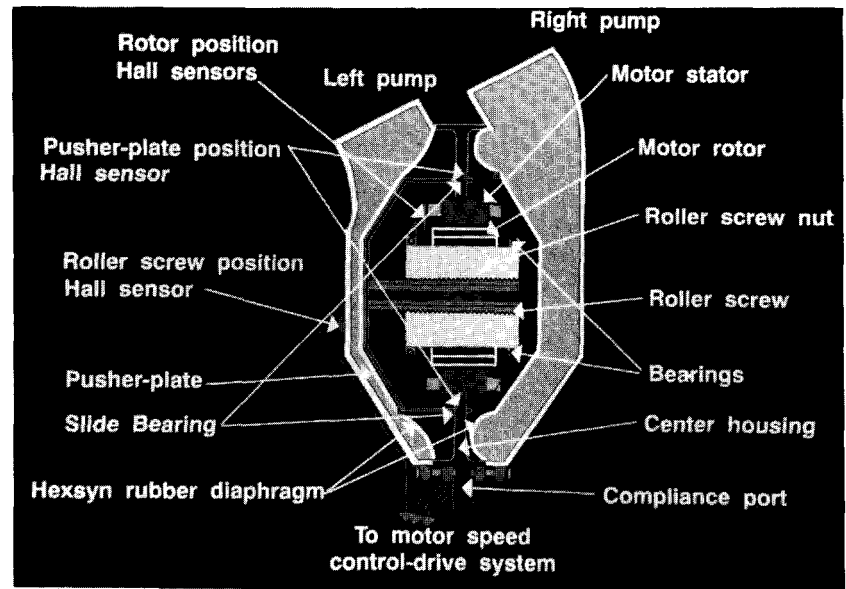


FIG. 2. Assembled electromechanical TAH.

FIG. 3. Schematic drawing of the Baylor electromechanical TAH.



stabilizing arms passing through the Teflon bearings of the center piece was attached at the left end of the roller screw. The maximum stroke length is limited to 0.52 inch. A circular hole is cut through the center of the roller screw, through which the pusher-plate shafts are guided. The roller screw is decoupled from the pusher-plate, thus allowing the pumps to fill passively.

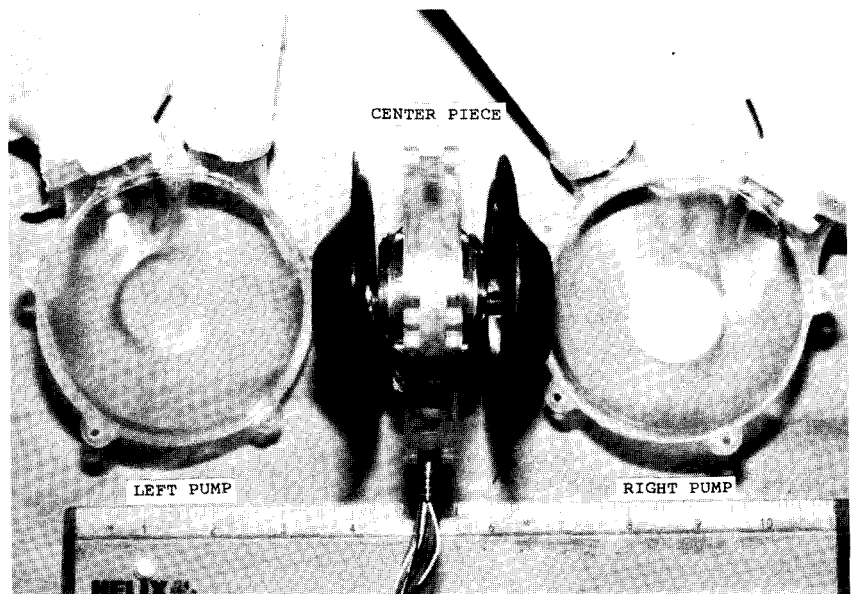
Control-drive system

Figure 5 shows a schematic diagram of the control-drive system. Three sets of Hall effect sensors are

used to control the motor speed and to run the left and right pumps in the left master alternate (LMA) mode (9). The first is the rotor commutation sensor. Since the motor is a three-phase and 14-pole brushless DC motor, three Hall sensors are placed at the edge of the motor rotor to detect the rotor position.

The second is the roller screw position sensor; a magnet was mounted in the circular plate attached at the left end of the screw, and the corresponding sensor was mounted on the outside of the left pump housing. The end-systolic levels of the left and right pumps were thus controlled from this signal; these

FIG. 4. Left and right pump housings with inflow and outflow cuffs and grafts, and center piece with an actuator with conically shaped pusher-plates and Hexsyn rubber diaphragm before assembly.



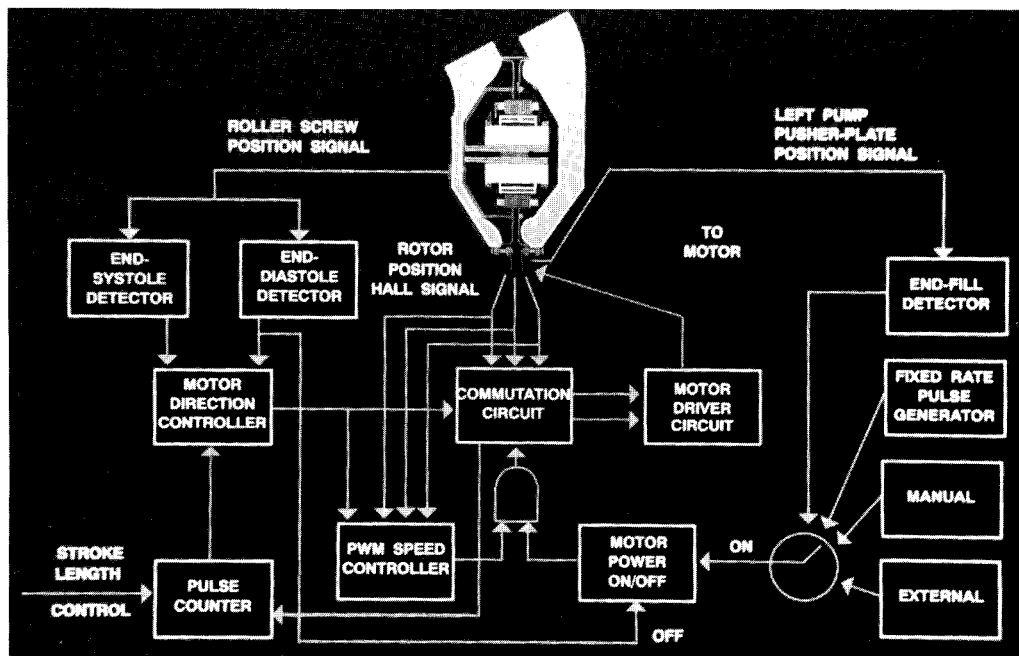


FIG. 5. Block diagram of the control-drive system developed to run both TAH and ventricular assist device.

trigger signals were used to reverse the motor rotation and to turn the motor power on or off. As the backup of the roller screw position sensor, a circuit to count the commutation pulses and to control the stroke length was also added to the system. When the system is started, the pulse-counting circuit is synchronized to the roller position signal to obtain absolute position of the rotor.

The third is the pusher-plate position sensor. The magnets were mounted on the inside edge of the pusher-plate, and corresponding Hall sensors were mounted in the center piece. These signals were used to monitor filling of both pumps and to obtain stroke volume information. When the TAH was run in the LMA fill-empty or variable rate (VR) mode, the left fill signal was used to turn on the motor power and to start the cycle. In this mode, the pump rate varied depending on the left fill rate. In the fixed rate (FR) mode, the internal pulse generator controlled the rate.

The motor speed was controlled through the pulse width modulation technique with the feedback signal controlling the power input to the motor. Bilevel speed control, separately on the left and right owing to differences in the left and right afterload, was incorporated to respond to changes in each preload.

Human anatomic fit study

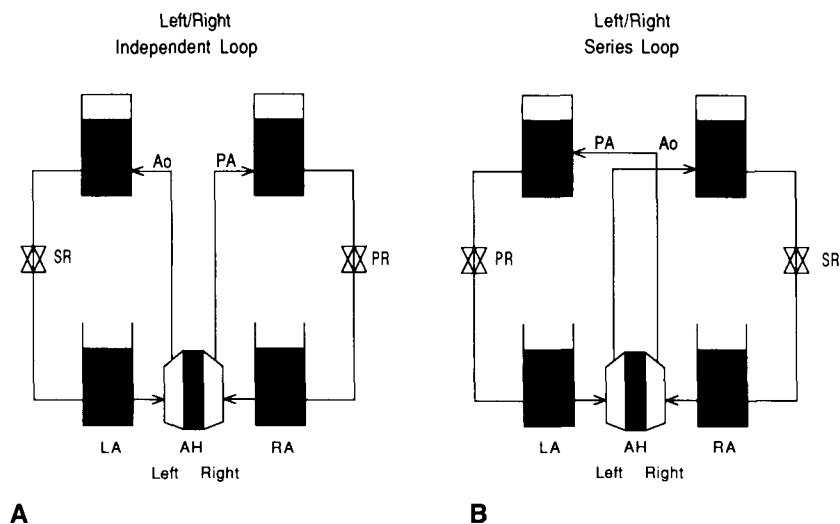
Because of the limitations of using human cadavers, radiographs, and computed tomography, the

fitting study for the Baylor TAH was carried out in orthotopic heart transplant recipients. Intraoperatively, after resection of the heart, the space available to accommodate the TAH was quantitated. The room temperature vulcanizer (RTV) model of the TAH was inserted in the pericardial space to evaluate the fitness and to match the direction of the inflow and outflow ports of the left and right pumps to the remnant atria and great vessels (10,11).

In vitro pump performance study

The pump performance was evaluated in two steps; initially the pump output of each ventricle was obtained as a function of the preload for given afterload in the left and right separate loop shown in Fig. 6A. In this loop, the operating condition of one ventricle could be fixed at a certain level while obtaining the performance of the other ventricle. The pump output of each ventricle as a function of the preload, the total power input to the motor, and the system efficiency defined as the power output of the two ventricles divided by the power input to the motor were derived as a function of the preload. In the second study, the output of the right ventricle was fed into the inflow reservoir of the left pump, and that of the left ventricle into the right inflow reservoir (Fig. 6B). In this loop, dynamic performance of the system with a sudden change in the preload, particularly the performance of the LMA mode, was evaluated.

FIG. 6. Block diagram representation of the left and right independent mock loop (A) and left and right series loop (B).



In vivo study

Through right thoracotomy at the fifth intercostal space, a female calf of 90 kg weight was placed on cardiopulmonary bypass (CPB) support. The natural heart was removed, and inflow and outflow connectors were sutured to the respective remnant atria and great vessels. The TAH was then connected, air was removed, and the TAH was started. The CPB was gradually terminated with the TAH maintaining the entire circulation. Postoperatively, right and left atrial and pulmonary and systemic arterial pressures, using the fluid-filled catheters connected with the disposable pressure transducers, left and right pusher-plate stroke signals, and roller screw position signal, were recorded continuously on an eight-channel polygraph. The experiment was terminated one week postoperatively to examine the overall status of the system, particularly evidence of mechanical wear in the actuator and thrombus formation on the blood-contacting surface.

RESULTS

The anatomic fit study was carried out in a total of 26 orthotopic cardiac transplant recipients (mean body weight 78 kg and surface area 2.0 m²) (10,11). A reasonably good fit of the RTV model in the pericardial space was obtained. There was no noticeable compression by the device on the adjacent organs.

Figure 7A shows the pump outputs in the FR and VR modes versus preload whereas Fig. 7B shows the power input to the motor, power output of the two ventricles, and efficiency of the system. The TAH can provide flows of 3–8 L/min against the left and right afterloads of 100 and 25 mm Hg with a filling pressure of 1–10 mm Hg. The required power

ranged from 7 to 14 W, and efficiency varied from 15 to 18%. The maximum afterload the TAH could work against was approximately 170 mm Hg. Figure 8 shows the response of the LMA mode to sudden change in the right atrial pressure in the VR and FR modes. In the FR mode, the right pump stroke increased, resulting in the right pump flow, followed by an increase in the left atrial pressure and consequent reduction in the right atrial pressure. In the VR mode, the sudden increase in right atrial pressure again increased the right pump stroke, elevating the left atrial pressure, which was followed by an increase in the pump rate and consequently an increase in the left pump flow and reduction in the right atrial pressure. Figure 9 summarizes the changes in the right and left atrial pressure and left and right pump flow changes following the sudden increase in right atrial pressure in the VR mode.

For the in vivo evaluation, the entire circulation of the calf was successfully maintained with the TAH for one week. Figure 10 shows the hemodynamic trace of the calf, indicating that all the parameters were regulated within physiological ranges. Figure 11 shows the internal surface of the left pump at autopsy. No thrombus was found inside the pumping chamber. Good anatomic fit was demonstrated (Fig. 12); there was no compression of the superior and inferior venae cavae and no kinking in the outflow grafts anastomosed to the great vessels.

DISCUSSION

The project aiming for development of totally implantable electromechanical artificial heart systems was initiated in 1990 at Baylor College of Medicine. The best features of each TAH currently being de-

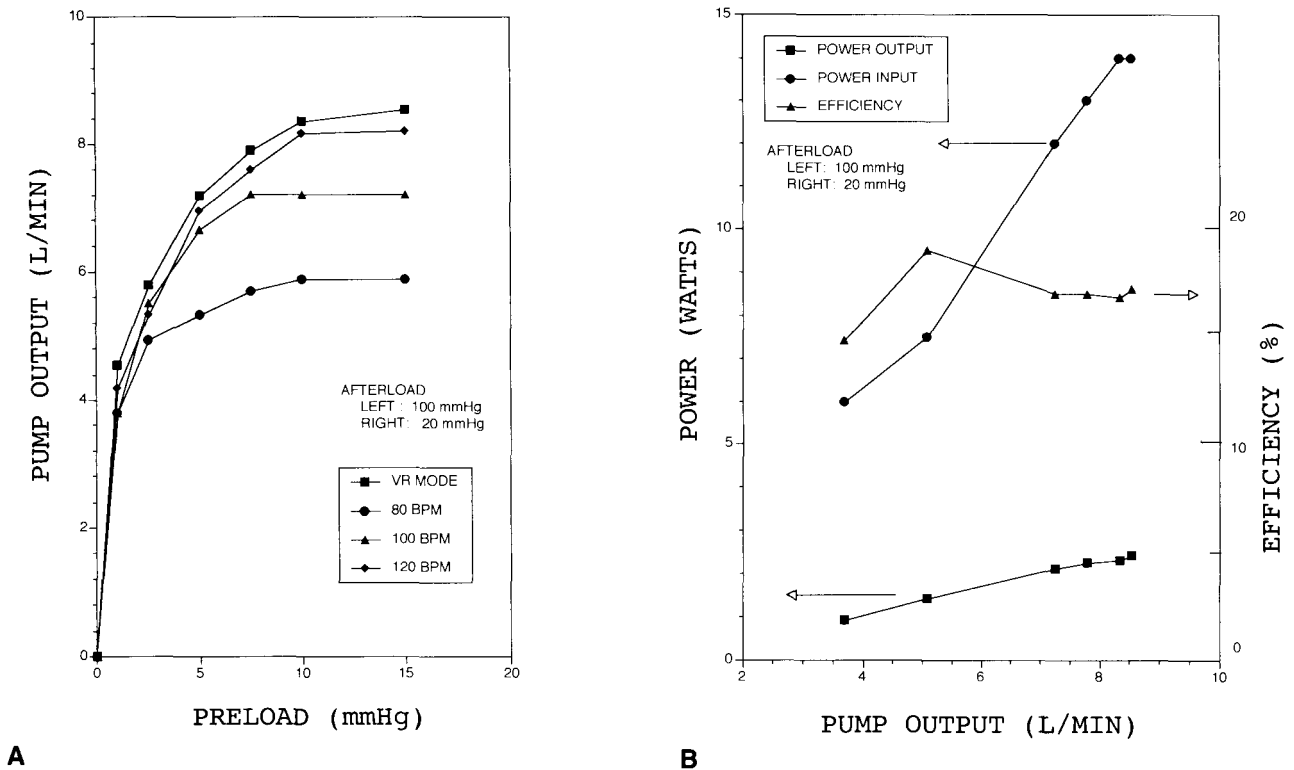
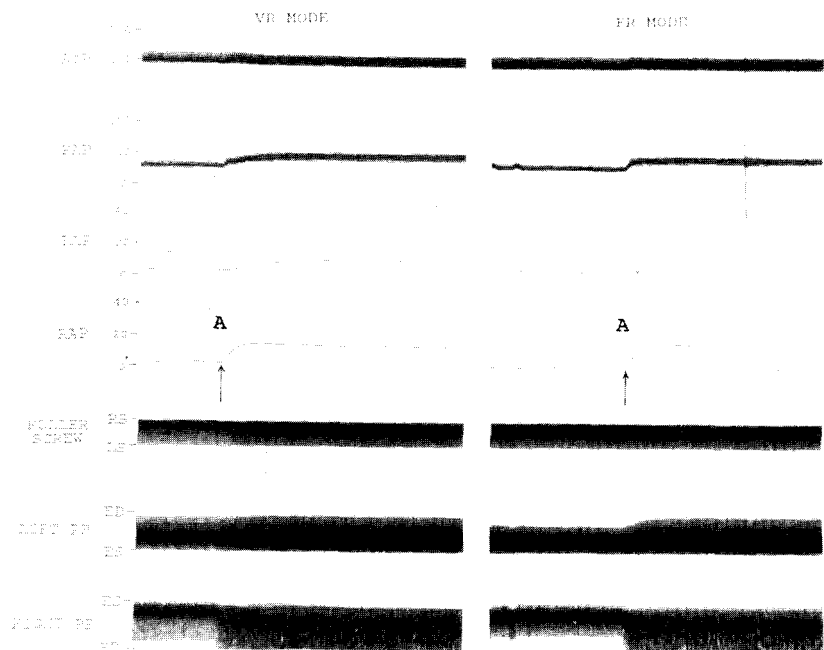


FIG. 7. Pump performance of the electromechanical TAH. **A:** Left pump output in the VR and FR (80, 100, and 120 bpm) modes with the left and right pump afterload fixed at 100 and 20 mm Hg. **B:** Power input to the system without a transcutaneous transformer system, hydraulic power output of the TAH, and efficiency of the system as a function of the pump output.

FIG. 8. Chart trace of the dynamic response of the left master alternate mode to sudden change in the right pump filling pressure in the VR (left) and FR (right) modes. At point A volume loading to the right atrial reservoir was performed. In the VR mode, right pump stroke volume increased immediately, followed by an increase in the left atrial pressure (LAP) and pumping rate. While in the FR mode, gradual increase in the LAP was followed by increase in the left pump stroke volume.



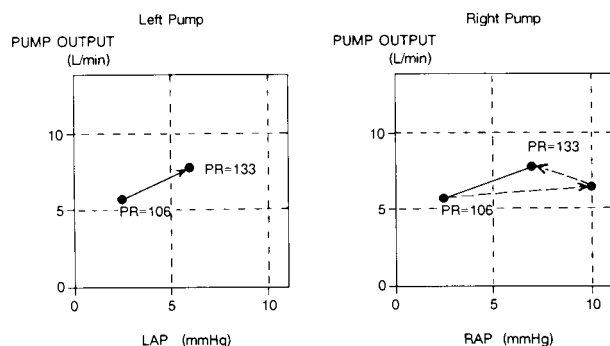


FIG. 9. Graphical representation of the dynamic response of the LMA mode to sudden change in the right atrial pressure. With the sudden increase in the right atrial pressure from 2.5 to 10 mm Hg, the right outflow increased from 5 to 6 L/min. The left atrial pressure gradually increased, followed by an increase in the pumping rate. The pump operating condition stabilizes at 133 bpm with the left and right atrial pressure at around 6 mm Hg. In this way, a new equilibrium point was reached.

veloped under National Institutes of Health support were incorporated in our design to develop a most realistic and workable system within a short duration. The multipurpose system concept was applied to utilize the same component between the TAH and the ventricular assist device. As a result, a compact and lightweight, simple and durable, high-perfor-

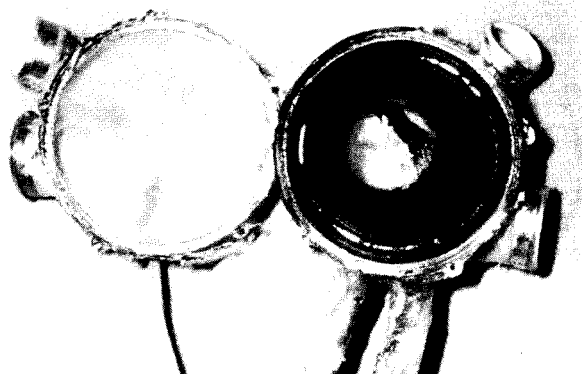


FIG. 11. Blood-contacting surface of the left pump after one week of implantation in a calf.

mance and efficient, easy-to-control and long-term-biocompatible TAH was developed. Table 1 summarizes the key features of the Baylor TAH.

From the standpoint of compact and lightweight design, the conical shape of the pusher-plate allowed us to integrate the actuator inside the one-piece design and to optimize the overall volume. In comparison to the previous design (12), the distance between

FIG. 10. Hemodynamic trace of the calf supported by the Baylor TAH. AoP, aortic pressure; PAP, pulmonary arterial pressure; LAP, left atrial pressure; RAP, right atrial pressure; Rt. E-S and Lt. E-S, right and left end-systolic position of the roller screw; E-S and E-D, end-systolic and end-diastolic position of the pusher-plate.

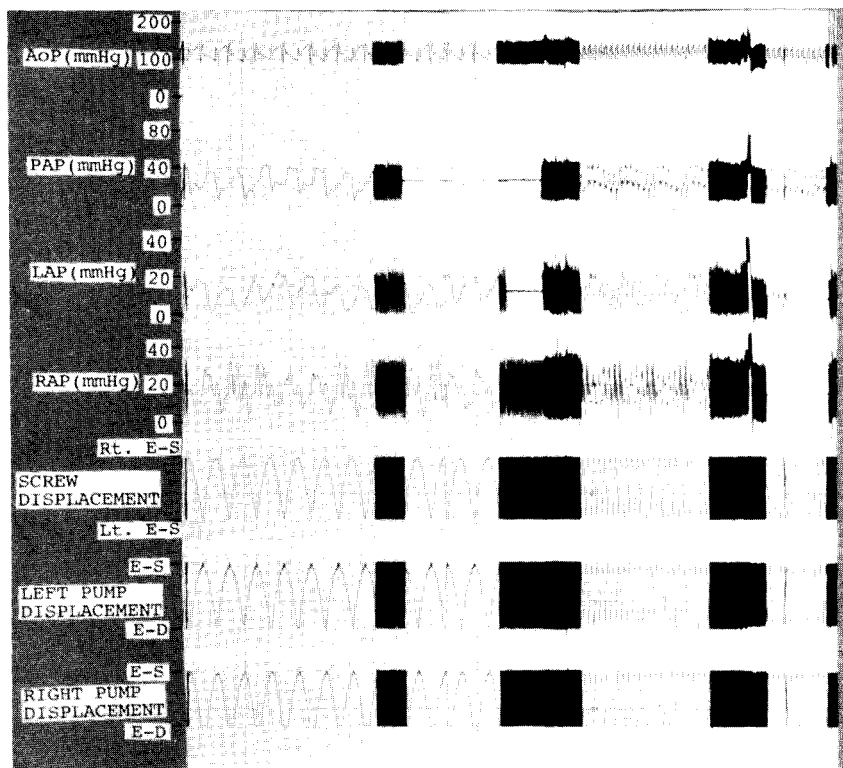


FIG. 12. Autopsy finding of the pump fit inside the thorax.



the left and right inflow ports was minimized to 40–45 mm to meet anatomical constraints. The overall volume (510 cc) and weight (620 g) approached those of the natural heart. The fitting study in orthotopic heart transplant recipients revealed that the current design will fit in patients having body weight of 78 kg and surface area and 2.0 m². The device also fit well in the thorax of the 80–90 kg calf.

The simple and durable design was achieved by using a DC brushless motor and a planetary roller screw as an actuator and Hexsyn rubber as flexing diaphragm. The planetary roller screw has demon-

strated long-term industrial performance. Rosenberg et al. (13) successfully used a roller screw to develop a one-piece TAH with sac-type pumps and reported survival of the test animal for 205 days. Also, Hexsyn rubber has demonstrated flex life over 350 million cycles, which is six to seven years. Thus, this combination can yield the long-term fail-safe operation required for a permanent device.

High performance and high efficiency were achieved through utilization of a high-efficiency actuator (mechanical efficiency of the roller screw is 95%) in combination with a large-orifice 27 mm tri-

TABLE 1. Key features of the Baylor electromechanical TAH

Compact and lightweight	One-piece design Conically shaped pusher-plate Stroke vol 63 cc Overall vol 510 cc Weight 620 g
Simple and durable design	DC brushless motor and planetary roller screw actuator Hexsyn rubber diaphragm
High performance, efficiency	Trileaflet inflow valve, 27 mm Passive fill High-efficiency roller screw Preload 1–10 mm Hg Pump output 3–8 L/min Power input 8–14 watts Efficiency 18–14%
Easy to control	Hall effect position sensor Left master alternate mode
Biocompatibility	Dry gelatin Gas sterilization Easy storage Good biocompatibility

leaflet inflow valve. The TAH showed extremely good sensitivity to the preload in the passive fill mode. With a filling pressure of 10 mm Hg, the TAH can attain maximum flow of more than 8 L/min. Although the design stroke volume was reduced to 63 ml from the original 70 ml, the reduced design can meet the maximum flow requirement of 8 L/min as specified by the National Institutes of Health with excellent anatomic configuration. Thus, from volume and energy utilization points of view, the current system approached high efficiency.

As for controllability of the device, the Hall effect sensor has already demonstrated durability and stability without requiring recalibration after implantation, and can yield effective information to control the pump performance (9). The LMA ejection mode was easily implemented utilizing the Hall effect stroke signal with the right pump operated in the fill-limited mode. The left pump fill trigger level was adjusted to run the right pump at 80% of the full stroke. In this way, increase in the right atrial pressure results in increase of the right pump stroke volume, increase in the left atrial pressure, and consequent increase in the pumping rate. For preload below 10 mm Hg, this control scheme yielded good pump output sensitivity in response to increase in right atrial pressure. However, when the preload exceeded 10 mm Hg and when the pumps were operated at full stroke, the stroke volume of the right pump was made smaller than the left by 10%–15%. The built-in "play length" of the left pump stroke allowed this adjustment without affecting the left stroke volume.

To provide long-term clot-free operation, the blood-contacting surface was biolized with a thin coating of calf-skin gelatin treated with 5% glutaraldehyde. Moreover, the dry gelatin technique was developed to circumvent the shortcomings of the wet gelatin including sterilization and storage problems. During in vivo study, the dry gelatin was easily sterilized using ethylene oxide gas and rehydrated before implantation. The blood pump surface after one week of implantation in the calf showed no thrombus formation.

In conclusion, a compact, durable, high-performance, easy-to-control, and biocompatible TAH intended for permanent human use was developed; its

in vitro and short-term in vivo performance meet the design specifications. The compact TAH is now ready for long-term evaluation in animals.

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